IN THE UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF OKLAHOMA

PATRICIA A. STAFFORD,	)	
	)	
Plaintiff,	)	
	)	
v.	)	No. CIV-02-1118-L
	)	
WYETH,	)	
	)	
Defendant.	)	

O R D E R

On July 12, 2002, plaintiff, Patricia A. Stafford, filed this action for damages in the District Court of Oklahoma County. Plaintiff alleges that she was injured as result of her use of the prescription diet drug Pondimin,[1] which was manufactured and distributed by predecessors of defendant Wyeth,[2] a Delaware corporation with its principal place of business in New Jersey.[3] On September 15, 1997, Wyeth withdrew Pondimin from the United States market. In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig., 2000 W.L. 122042 at *3 (E.D. Pa.

[1]Pondimin is Wyeth's trade name for the drug fenfluramine. When fenfluramine was prescribed in combination with the drug phentermine, it was commonly referred to as Phen-fen.

[2]On August 3, 1998, the manufacturer of Pondimin, A.H. Robins Company, Inc., was merged into American Home Products Corporation ("AHPC") and ceased to exist as a separate company. On March 11, 2002, AHPC changed its name to Wyeth. Defendant Wyeth's Answer to Plaintiff's Petition at 1 n.1. All references to Wyeth in this Order include its predecessors in interest.

[3]In the state court action, plaintiff also named as a defendant the physician who prescribed Pondimin to her, James A. Hill, M.D. On September 18, 2002, the court issued an Order denying plaintiff's motion to remand; thereafter, Dr. Hill was dismissed from this action.

Aug. 28, 2000). Thereafter, in response to a wave of litigation, the Judicial Panel on Multidistrict Litigation ordered coordinated pretrial proceedings before the Honorable Harvey Bartle III in the Eastern District of Pennsylvania. In re Diet Drugs., 990 F. Supp. 834, 836 (J.P.M.L. 1998). On August 28, 2000, Judge Bartle approved a nationwide class action settlement, which permitted class members to file suit for limited downstream opt-out claims. In re Diet Drugs, 2000 W.L. 122042 at *68-69. (E.D. Pa. Aug. 28, 2000). Pursuant to the settlement agreement, plaintiff presents intermediate opt-out claims for valvular heart disease ("VHD"). Plaintiff's Original Petition at ¶ 7(d). She asserts four claims against defendant: negligence, design defect, failure to warn, and misrepresentation. Id. at ¶¶ 47-74.

This matter is before the court on defendant's motion for summary judgment. Summary judgment is appropriate if the pleadings, affidavits, and depositions "show that there is no genuine issue as to any material fact and the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). Any doubt as to the existence of a genuine issue of material fact must be resolved against the party seeking summary judgment. In addition, the inferences drawn from the facts presented must be construed in the light most favorable to the nonmoving party. Board of Education v. Pico, 457 U.S. 853, 863 (1982). Nonetheless, a party opposing a motion for summary judgment may not simply allege that there are disputed issues of fact; rather, the party "must set forth *specific* facts showing that there is a genuine issue for trial." Fed. R. Civ. P. 56(e) (emphasis added). *See also*,

Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249 (1986). "[T]here is no issue for trial unless there is sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party. If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." Anderson, 477 U.S. at 249-50 (citations omitted). In addition, "the plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986).

As plaintiff's claims all hinge on defendant's alleged failure to warn, she must establish both that Pondimin in fact caused her injury and that Wyeth's failure to warn was the proximate cause of her injury. Eck v. Parke, Davis & Co., 256 F.3d 1013, 1017 (10th Cir. 2001). With respect to prescription drugs, Oklahoma has adopted the "learned intermediary" doctrine.

> Where a product is available only on prescription or through the services of a physician, the physician acts as a "learned intermediary" between the manufacturer or seller and the patient. It is his duty to inform himself of the qualities and characteristics of those products which he prescribes for or administers to or uses on his patients, and to exercise independent judgment, taking into account his knowledge of the patient as well as the product. The patient is expected to and, it can be presumed, does place primary reliance upon that judgment. The physician decides what facts should be told to the patient. Thus, if the product is properly labeled and carries the necessary instructions and warnings to fully apprize the physician of

> the proper procedures for use and the dangers involved, the manufacturer may reasonably assume that the physician will exercise the informed judgment thereby gained in conjunction with his own independent learning, in the best interest of the patient.

Edwards v. Basel Pharms., 933 P.2d 298, 300-01 (Okla. 1997) (*quoting* Wooderson v. Ortho Pharm. Corp., 681 P.2d 1038, 1052, *cert. denied*, 469 U.S. 965 (1984)). In a failure to warn case such as this, plaintiff is entitled to a rebuttable presumption that her physician would have read and heeded an adequate warning had one been given.[4] Eck, 256 F.3d at 1018. Wyeth may rebut this presumption "by establishing that although the prescribing physician would have 'read and heeded' the warning or additional information, this would not have changed the prescribing physician's course of treatment." Id. at 1019.

Based on the undisputed facts, Wyeth has rebutted this presumption. Those facts establish that Dr. Hill prescribed Pondimin to plaintiff from June 1996 through March 1997. Affidavit of Patricia A. Stafford at ¶ 1. "Had additional warnings been issued by Wyeth warning of an alleged association between Pondimin and VHD and of an alleged increased risk of [primary pulmonary hypertension] associated with Pondimin usage, James A. Hill, M.D., would not have changed his decision to prescribe Pondimin to Plaintiff."[5] Dr. Hill was unequivocal in his recent deposition

[4]For purposes of ruling on defendant's motion for summary judgment, the court assumes without deciding that plaintiff can establish the warnings given by Wyeth were inadequate.

[5]Defendant Wyeth's Motion for Summary Judgment at 2. Contrary to LCvR 56.1(c), plaintiff did not specifically controvert either statement of material fact presented by defendant, including the statement quoted in the text. Pursuant to the court's Local Civil Rules, this statement is

testimony in this case: based on plaintiff's height, weight, and risk factors, if Pondimin were available today, he would prescribe it to her.

> Q. If the medical records showed that Mrs. Stafford was 5'1 and 172 pounds with a history of hypertension and a family history of heart disease, would you consider her to be a candidate for anorexic drugs?
>
> A. Yes.
>
> Q. (By Mr. Wolfe) And is that because weight loss helps patients gain control of hypertension?
>
> A. Absolutely.
>
> Q. And also helps in connection with heart disease?
>
> A. Yes.
>
> * * *
>
> Q. Knowing what you know today, would you still prescribe, if you were in practice, Redux or Pondimin to a group of patients that you considered by be candidates for diet drug medication?
>
> A. Yes.
>
> * * *
>
> Q. (By Mr. Wolfe) Given those facts, if those medications were available today, knowing what you know today, would you prescribe to a woman of that height and weight with a family of heart disease?
>
> A. Yes.

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therefore "deemed admitted for the purpose of summary judgment". LCvR 56.1(c).

Deposition of James A. Hill, M.D. at 8, 43, 50 (form objections omitted). This testimony is clearly sufficient to rebut the presumption that, had Dr. Hill been properly warned, he would have read and heeded the warning. *See* Eck, 256 F.3d at 1021.

The presumption therefore disappears and plaintiff must come forward with sufficient evidence to withstand summary judgment. Woulfe v. Eli Lilly & Co., 965 F. Supp 1478, 1483 (E.D. Okla. 1997). "To submit the case to a jury, [plaintiff] must either discredit the physicians' testimony or call into question the substance of the testimony, or otherwise demonstrate that the alleged failure to warn was the proximate cause of [her] injuries." Eck, 256 F.3d at 1019. Plaintiff attempts to satisfy her burden in three ways. First, she argues that she would not have agreed to take Pondimin if Wyeth had adequately warned Dr. Hill of the risks associated with the drug. Second, she contends Dr. Hill's testimony that he would have prescribed Pondimin to plaintiff is speculative and contradicted by other deposition testimony. Finally, plaintiff claims that no reasonable doctor would have prescribed Pondimin if Wyeth had provided proper warnings.

None of plaintiff's arguments, however, creates a triable issue as to proximate cause. Plaintiff's assertion that she would not have taken Pondimin if Wyeth had provided adequate warnings misconstrues the learned intermediary doctrine. Under that doctrine, Wyeth's duty to warn ran to plaintiff's physician, not to plaintiff herself. Eck, 256 F.3d at 1017-18; Woulfe, 965 F. Supp. at 1482. Moreover, the learned

intermediary doctrine assumes that the treating physician will heed any warnings given, that is, that the doctor will incorporate those warnings into the risk/benefit analysis in deciding whether to prescribe a given drug. The physician's heeding the warning does not mean that the warning is necessarily passed on to the patient. *See* Eck, 256 F.3d at 1021. Plaintiff's affidavit is, therefore, irrelevant. Likewise irrelevant is plaintiff's argument regarding what a reasonable physician would do. The question in the learned intermediary context is not what an objective physician would decide, but rather what plaintiff's doctor would determine based on his knowledge of the drug in question and the plaintiff's risk factors. *See* Woulfe, 965 F. Supp. at 1484-85. Although Dr. Hill has no specific memory of plaintiff,[6] plaintiff does not dispute that he was adequately informed of her height, weight, and risk factors during his deposition. Dr. Hill's knowledge of the risks of obesity – including diabetes, heart disease, and hypertension – is also not controverted. Likewise, plaintiff does not contend that Dr. Hill's current knowledge of the increased risk of valvular heart disease is inadequate to conduct a proper risk/benefit analysis.[7] Thus, his risk/benefit analysis testimony is neither speculative nor discredited.

[6]Deposition of James A. Hill, M.D. at 8.

[7]Dr. Hill testified that after Pondimin was withdrawn from the market he read an AMA newsletter reporting on studies discussing the association between Pondimin and valvular heart disease. Deposition of James A. Hill, M.D. at 44-45. He considers valvular heart disease to be a serious medical side effect and therefore would have incorporated that into his risk/benefit analysis. Id. at 39, 42.

Finally, the court concludes that plaintiff has failed to call into question Dr. Hill's credibility. Plaintiff contends that Dr. Hill's testimony in this case is contradicted by deposition testimony given in 2003 in McKee v. Wyeth, Case No. CIV-02-1119-C (W.D. Okla. filed Aug. 14, 2002). In McKee, Dr. Hill testified that he would not prescribe Pondimin if it were currently on the market and would not have prescribed it in 1995 had he known all the side effects. Plaintiff's Exhibit 5, Deposition of James Hill, M.D. in McKee v. Wyeth at 87-88. There is, however, no indication in the record that Dr. Hill's risk/benefit analysis for Ms. McKee would have been comparable to the analysis for plaintiff in this case. Furthermore, Dr. Hill's prior testimony does not alter his unequivocal testimony in this case that – knowing all the side effects and risks – he still would have prescribed Pondimin for *this* patient.

As there is no evidence to contradict Dr. Hill's statement that he would have prescribed Pondimin to plaintiff, plaintiff cannot establish Wyeth's failure to warn was the proximate cause of her injury. Defendant Wyeth's Motion for Summary Judgment (Doc. No. 55) is therefore GRANTED. Judgment will issue accordingly.

It is so ordered this 26th day of January, 2006.

Tim Leonard

TIM LEONARD
United States District Judge